

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/535,500 Confirmation No.: 7327
Applicant : Anne Mette Buhl HERTZ, et al.
Filed : May 26, 2005
Title : METHODS AND KITS FOR DIAGNOSING AND TREATING B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA
TC/Art Unit : 1643
Examiner: : Anne Gussow

Docket No. : 55320.001041
Customer No. : **21967**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME AND RESPONSE TO RESTRICTION

Sir:

Applicants respectfully petition for a Two-Month Extension of Time under 37 C.F.R. § 1.136(a) for responding to the Restriction Requirement mailed on April 23, 2007, thereby extending the time for the response until July 23, 2007 in the above-captioned application. Applicants submit herewith the fee amount of \$450.00, for the two-month extension of time (large entity).

Responsive to the Restriction Requirement mailed on April 23, 2007, Applicants wish to elect Group I with traverse. The traversal is on the basis that the Restriction Requirement violates the PCT rules and US restriction practice governing patent applications filed under 35 USC 371 since it is in conflict with Article 127(1) of the PCT wherein it is stated that no national law shall require compliance with requirements correlating to the form or context of the international application different from or additional to those in which are provided in the Treaty and the Regulations. Article 27(1) is further clarified in the PCT guidelines under Item 138, wherein it is stated that an international application which complies with the unity of invention requirement laid down in Rule 13 PCT must be accepted in all the designated and elected offices.

With respect thereto, Applicants note that this application is a US national filing under 35 USC 371 based on PCT application WO 2004/04376. Therefore, the Restriction Requirement herein must adhere to the governing PCT regulations.

Contrary to the Examiner's alleged reasons for restriction, the applicant does not agree with the suggestion that the "diagnostic part" of the present invention and the single general inventive concept pertaining thereto, merely relate to Group I. To the contrary, it is commonly known in the relevant art relating to lymphoma that a method for the establishment of a "prognosis" as claimed of a subtype of B-CLL simply cannot be made without having first established a diagnosis of the disease in an individual. Therefore, neither the method for establishing a diagnosis, nor the method for establishing the prognosis can be performed without the specific knowledge as to the at least one expression product (comprising at least one nucleotide sequence selected from the group consisting of SEQ ID NO: 12, 13, 14, 15, 16, 17 and 18 or the corresponding polypeptide). Accordingly, at the very least Group I and Group II should be rejoined and examined together as they pertain to a single invention joined to form a single unitary inventive concept as above-explained.

Moreover, Applicants respectfully submit that Group VI should also be included therewith as it is also within the general inventive concept of providing a diagnosis/prognosis of B-CLL based on evaluating the correlation of the biomarker/gene based on the same detected nucleotide and corresponding polypeptide sequence. Applicants further respectfully submit that by detecting either the DNA or polypeptide is functionally equivalent as both are detecting the expression of the same biomarkers that correlate to the B-CLL disease. Indeed the nucleic acid sequence defines the corresponding polypeptide sequence.

Therefore, Applicants respectfully request that Groups I, II and VI should be rejoined and examined together in response to the Election response submitted herewith. Further, in order to expedite prosecution on the merits Applicants herein are canceling claims 1-42 without prejudice and are submitting new claims 43-60 all of which are believed to correspond to the elected subject matter which defines a unitary invention according to the PCT guidelines as described above.